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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

RICHARD RODRIGUEZ, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. GRITSTONE BIO, INC., ANDREW R. ALLEN, AND VASSILIKI ECONOMIDES, Defendants.	Case No. 3:24-cv-3640 CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS DEMAND FOR JURY TRIAL

Court-appointed Lead Plaintiff Richard Rodriguez and Additional Plaintiff Tammy Beal ("Plaintiffs"), individually and on behalf of all others similarly situated, by Plaintiffs' undersigned attorneys, for Plaintiffs' complaint against Defendants, allege the following based upon personal knowledge as to Plaintiffs' own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiffs' attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Gritstone bio, Inc. ("Gritstone" or the "Company"), analysts' reports and advisories about the Company, consultation with experts, interviews with confidential witnesses, and information readily obtainable on the Internet. Plaintiffs believe that substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Gritstone securities between March 9, 2023 and April 2, 2024, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company.

2. Founded in 2015, Gritstone is a clinical-stage biotechnology company that claims to develop "next generation" vaccines through its "proprietary," novel "self-amplifying mRNA," which the Company refers to as "samRNA." In 2021, Gritstone began its "CORAL program" to test the Company's theory to develop a samRNA-based vaccine to combat COVID-19. In 2023, the Company praised the CORAL Phase 1 results as

demonstrating the vaccine was well-tolerated and "capable of driving strong, potentially durable and broad immunogenicity" response.

3. To get one step closer to commercialization, Gritstone set its sights on initiating the CORAL Phase 2 study. Throughout the Class Period and beyond, the Company repeatedly assured investors that its in-house manufacturing processes (and the manufacturing processes of any third-party contractors) were compliant with the "current Good Manufacturing Practices" ("cGMP") that the FDA requires for all such Phase 2 studies. The Company lauded its "fully integrated GMP manufacturing" capabilities, noting "[w]e manufacture our products at our own fully-integrated good manufacturing practice (GMP) biomanufacturing facilities," and this "ability to control the manufacturing of high-quality vaccine products … is critical for efficient clinical development and commercialization."

4. Because Gritstone has no commercial-stage products, the vast majority of its vaccine programs are funded via external collaborators, such as through nonprofits and government grants. Indeed, throughout its history, the Company has not generated any revenue from product sales and does not expect to generate any revenue from product sales for the foreseeable future, with all recognized gains flowing from those prior agreements. By 2023, the Company had incurred significant debt, prompting a "going concern" warning in August stating that "[t]he Company's cash, cash equivalents and marketable securities are not sufficient to fund the Company's planned operations for a period of 12 months."

5. A month later, in September 2023, the Company's cash problems appeared to be over when it was awarded a lucrative government contract from the Biomedical Advanced Research and Development Authority ("BARDA"), a component of the Administration for Strategic Preparedness and Response in the U.S. Department of Health and Human Services

("HHS"). Under the BARDA Contract, the Company "will receive funding of up to an estimated $433 million to conduct a 10,000 participant randomized [CORAL] Phase 2b comparative study evaluating the Company's next-generation self-amplifying mRNA vaccine candidate … to protect against COVID-19."

6. Critically—in conformance with the FDA's regulations—the Contract expressly required Gritstone to use cGMP standards in this government-funded CORAL Phase 2 study. The Contract also required that, for the Company to recognize any revenue from the BARDA Contract, Gritstone would need to "perform[] … certain milestones such as preparation of protocol synopsis and submission of an investigational new drug application" approved by the FDA before initiating the study. This deadline to meet this "base period of performance" was the end of Q1, from September 30, 2023, to March 31, 2024. In a press release announcing the Phase 2b CORAL Study, the Company boasted that the Contract "provides strong validation of [its] innovative vaccine platform in infectious diseases," that execution of the study would be fully funded by BARDA, and that the CORAL Phase 2 Study would be expected to launch in the first quarter of 2024.

7. But, unknown to investors, Gritstone did *not* have the necessary cGMP capabilities to comply with the BARDA Contract's timeline. Contrary to Gritstone's rosy statements assuring investors about the Company's robust cGMP manufacturing and processing capabilities, the Company was scrambling to procure the necessary cGMP materials for the CORAL Phase 2 vaccine program—even well before entering the Contract. A Quality Director confirmed that, as early as March 2023 six months before the BARDA announcement, management was well aware the Company did not have the ability to conduct the CORAL Phase 2 study with the necessary cGMP processes. Instead, the Company spent

2023 scrambling, and failing, to procure them—all the while representing to investors that the Phase 2 study was on track to meet the BARDA deadline. As Plaintiffs' pharmaceutical expert opines, however, when Gritstone announced the BARDA Contract in September of 2023, given the known lack of cGMP materials available throughout 2023 and the massive scale-up the BARDA-funded Phase 2 study required, the Company knew it could not meet the Q1 2024 trial start date. Indeed, the FDA had communicated these cGMP requirements directly to the Company when analyzing the CORAL study design, and (unknown to investors) had issued a clinical hold on the CORAL program for failure to comply with these cGMP mandates in December 2023.

8. Predictably for the Company (but not for investors), on February 12, 2024, Gritstone issued a press release announcing that the Company was delaying the launch of the CORAL Phase 2 Study until fall 2024 to purportedly "allow use of fully GMP-grade raw materials in the vaccine, which is expected to increase the regulatory utility of the trial." Soon after, on February 29, 2024, Gritstone issued a press release "announc[ing] an approximately 40% reduction of its workforce," stating that "[t]he move comes following the recently announced delay of the proposed CORAL Phase 2b study, which resulted in Gritstone not receiving external funding it previously anticipated beginning in 1Q 2024, associated with the initiation of the study." On this news, Gritstone's stock plummeted $0.78 per share, or 27.86%, to close at $2.02 per share on March 1, 2024.

9. Defendants continued to represent that the CORAL Phase 2 study, and the critical influx of BARDA-funded cash, was forthcoming as the Company "prepar[ed] to launch the study later" in 2024. But soon after, on April 1, 2024, the Company filed an 8-K announcing that "it has commenced an underwritten public offering of shares of its common

stock" to shore up the Company's dire cash position, a pronouncement that sent the stock falling $1.15 per share, or 48.94%, to close at $1.20 per share on April 2, 2024.

10. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiffs and other members of the Class have suffered significant damages.

II. JURISDICTION AND VENUE

11. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

13. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Gritstone is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' activities took place within this Judicial District.

14. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

III. PARTIES

15. Lead Plaintiff Richard Rodriguez, as set forth in his Certification (DE 22-5), acquired Gritstone securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

16. Additional Plaintiff Tammy Beal, as set forth in her Certification (attached hereto), acquired Gritstone securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

17. Defendant Gritstone is a Delaware corporation with principal executive offices located at 5959 Horton Street, Suite 300, Emeryville, California 94608. Gritstone's common stock trades in an efficient market on the Nasdaq Global Select Market ("NASDAQ") under the ticker symbol "GRTS."

18. Defendant Andrew R. Allen ("Allen") has served as Gritstone's President, Chief Executive Officer, and Director at all relevant times.

19. Defendant Vassiliki Economides ("Economides") has served as Gritstone's Executive Vice President and Chief Financial Officer at all relevant times.

20. Defendants Allen and Economides are collectively referred to herein as the "Individual Defendants."

21. The Individual Defendants possessed the power and authority to control the contents of Gritstone's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Gritstone's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Gritstone, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

22. Gritstone and the Individual Defendants are collectively referred to herein as "Defendants."

IV. SUBSTANTIVE ALLEGATIONS

A. Gritstone Promotes CORAL Program As A More Potent And Durable COVID-19 Vaccine.

23. Founded in 2015, Gritstone, is a clinical-stage biotechnology company that uses "immunological insights" with "proprietary technologies" and "capabilities" to develop "next-generation vaccines." (Annual Report for 2022, Form 10-K, filed March 9, 2023.) The Company is headquartered in Emeryville, California, with key functions located in Boston, Massachusetts and Pleasanton, California.

24. Gritstone's "unique approach" in developing these "next-generation vaccine" for infectious disease turns on its "application of self-amplifying mRNA," which the Company refers to as "samRNA." (Annual Report for 2022, Form 10-K, filed March 9, 2023.) Like "traditional mRNA vaccines, samRNA vaccines use the host cell's transcription system to produce target antigens to stimulate adaptive immunity," but "[u]nlike traditional mRNA, [with samRNA] the RNA replicates once inside the cell, theoretically leading to high and durable antigen expression." (Annual Report for 2022, Form 10-K, filed March 9, 2023.). Gritstone's "goal is to unlock more potent and durable immunity by harnessing vaccine innovation" by using this samRNA to "extend[]" the "duration" and "magnitude" of these vaccines. (Annual Report for 2022, Form 10-K, filed March 9, 2023.)

25. Gritstone's "CORAL program" tested the Company's theory to develop a samRNA-based COVID-19 vaccine. In 2021, Gritstone started CORAL "in response to emerging limitations of first-generation COVID-19 vaccines, and today, serves as proof-of-concept for our ability to drive more potent and durable responses than those of current

vaccines." (Annual Report for 2022, Form 10-K, filed March 9, 2023.) While with COVID-19 "immune responses can vary, viruses mutate, and neutralizing antibodies wane, necessitating re-dosing (boosters)," Gritstone is offering "[a]n approach capable of inducing a potent, broad immune response could have utility across a variety of viral" COVID-19 strains." (Annual Report for 2022, Form 10-K, filed March 9, 2023.) Thus, using samRNA, the Company theorizes that a CORAL vaccine "could offer the potential for more durable protection and broader immunity against SARS-CoV-2 [COVID-19]," theoretically offering patients more protection while suffering less repeat office visits to get the latest COVID booster shot. (Annual Report for 2022, Form 10-K, filed March 9, 2023.)

B. FDA Regulation Requires Gritstone's CORAL Phase 2 Study To Be Conducted Using cGMP-Grade Process and Materials.

26. Investigational drugs, including vaccines, typically progress sequentially through Phase 1, Phase 2, and Phase 3 clinical studies, each of which involves progressively more patients, time, and financial investment.

27. Early data from the CORAL program's Phase 1 studies were promising. For example, Gritstone reported that Phase 1 results showed its samRNA vaccines to be well-tolerated and "capable of driving strong, potentially durable and broad immunogenicity" response. According to the Company, results from these Phase 1 trials "demonstrate[] the potential ability of our vaccines to elicit potent and durable neutralizing antibody responses … provid[ing] early signals of the potential advantages of selfamplifying mRNA over first-generation mRNA." (Annual Report for 2022, Form 10-K, filed March 9, 2023.)

28. Current Good Manufacturing Practices ("cGMP") are a set of a regulations and policies that seek to ensure that pharmaceuticals meet quality standards so that they will be safe and effective when used as intended. cGMP regulations are generally applicable to

any drug intended for administration in humans or animals, including investigational-stage drugs that are administered in clinical trials.

29. More specifically, the FDA requires that "[w]hen drug development reaches the stage where the drug products are produced for clinical trials in humans or animals, then compliance with the cGMP regulations is required." In 2006, the FDA published a Final Rule which exempted Phase 1 trials from cGMP requirements, finding it "appropriate because many of the issues presented by the production of investigational drugs intended for use in the relatively small phase 1 clinical trials are different from issues presented by the production of drug products for use in the larger phase 2 and phase 3 clinical trials or for commercial marketing." (Federal Registry Notice, July 15, 2008.) A Phase 1 clinical trial simply involves "the initial introduction" of an investigational new drug product into humans and is "conducted to establish the basic safety of the drug," and "to determine the metabolism and pharmacologic actions of the drug in humans." These Phase 1 trials also typically have a small sample size population, where "[t]he total number of subjects … is limited generally to no more than 80 subjects." (Federal Registry Notice, July 15, 2008.) The patient numbers of the three CORAL Phase 1 studies reflected this: (1) for the CORAL-BOOST (healthy volunteers following primary series of currently approved COVID-19 vaccines), the total enrollment was 40; (2) for the CORAL-CEPI (vaccine-naïve healthy and HIV+ subjects in South Africa), total enrollment was 342; and for (3) CORAL-NIH (run by the National Institute of Allergy and Infectious Disease [NIAID] in previously vaccinated healthy volunteers), total enrollment was 81 patients.

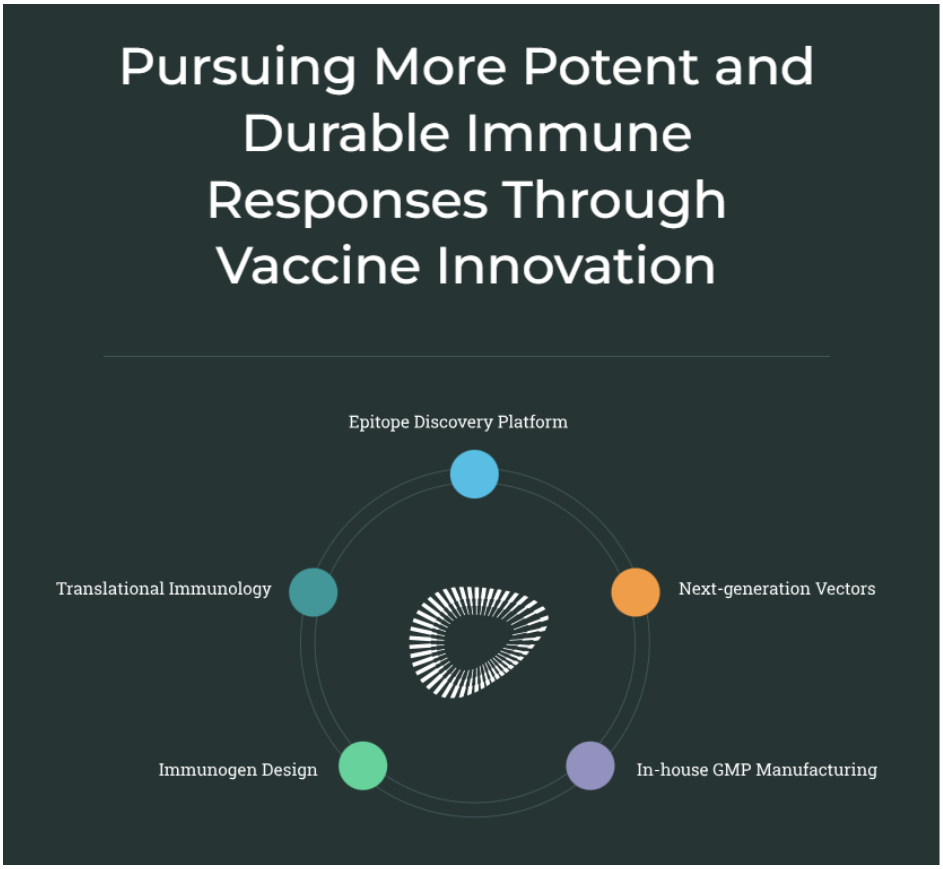
30. Because the CORAL studies were in Phase 1, the study did not need to meet the FDA's cGMP requirements. To get one step closer to commercialization, however,

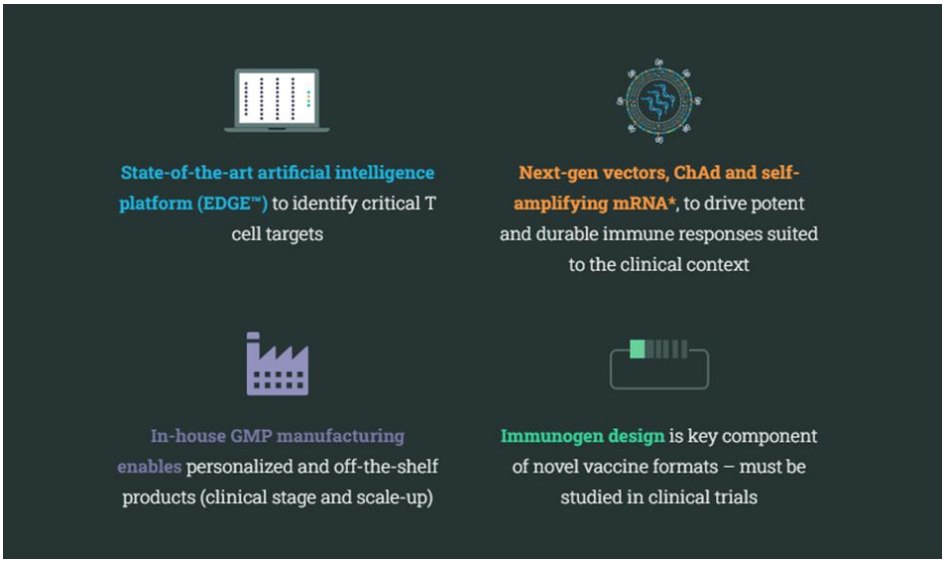
Gritstone set its sights on initiating the CORAL Program Phase 2 study. Unlike with Phase 1 trials, the FDA is clear that cGMP compliance is required for clinical trials conducted in Phase 2 and 3. As the FDA has reasoned, the process and procedures in Phase 1 are minimal "in contrast to phase 2 and phase 3 clinical trials" where "a substantially greater number of subjects are involved," many "more subjects are exposed to the drug product," and "the effectiveness of the drug product is also tested in addition to safety." (Federal Registry Notice, July 15, 2008.)

31. Because the FDA considers products (including vaccines) administered to humans during clinical trials under the authority of investigational new drug ("IND") applications trials, "drugs," such trials for these vaccines must be conducted in compliance with cGMP regulations. Whereas Phase 1 trials may be exempted under the 2006 Final Rule, Phase 2 and Phase 3 clinical trials are governed by the FDA guidance document, Preparation of Investigational New Drug Products. Under this mandate, the "FDA, while recognizing the differences between the manufacture of investigational products and commercial products, believes that it is nonetheless vital that investigational products [in Phase 2 and 3] be made in conformance with current good manufacturing practice (cGMP)." Thus, FDA regulations require any upcoming CORAL Phase 2 study to use cGMP process and materials.

C. Gritstone Misrepresents Its cGMP Manufacturing Processes and Capabilities.

32. Gritstone repeatedly touted its in-house manufacturing capabilities and the cGMP processes used for producing its vaccines. On the Company's website, Gritstone listed "in house GMP manufacturing" capacities as one of five core tenets underlying Gritstone's "unique approach."





33. As the Company's Annual Report for 2022, Form 10-K, filed March 9, 2023 ("Annual Report" or "10-K") pronounced, Gritstone would achieve its goal of producing innovative vaccines "by leveraging our in-house capabilities and technologies," noting "the speed, quality, reliability, and scalability of our manufacturing capabilities is a core

competitive advantage to our clinical development and potential commercial success." (Annual Report for 2022, Form 10-K, filed March 9, 2023.) To that end, Gritstone assured investors that it has "successfully internalized all biomanufacturing steps to drive down both cost and production time, as well as establish full control over … product quality." (Annual Report for 2022, Form 10-K, filed March 9, 2023.) "[O]perating our own manufacturing facility provides us with enhanced control of material supply for both clinical trials and the commercial market, will enable the more rapid implementation of process changes." (Annual Report for 2022, Form 10-K, filed March 9, 2023.) "We have invested significant resources in our Cambridge, Massachusetts sequencing lab and our Pleasanton, California biomanufacturing facility to address these needs and position ourselves to control the critical steps in the production of our" vaccines. (Annual Report for 2022, Form 10-K, filed March 9, 2023.)

34. Gritstone represented that it conducted these "in-house" process complying with cGMP. In the Company's 10-K, it lauded its "fully integrated GMP manufacturing" capabilities. Under the header, "**In-house GMP Manufacturing**," the 10-K relates that: "***We manufacture our products at our own fully-integrated good manufacturing practice (GMP) biomanufacturing facilities***." (Annual Report for 2022, Form 10-K, filed March 9, 2023.) The Company also noted that this "ability to control the manufacturing of high-quality vaccine products, and scale production, if early data are positive, is critical for efficient clinical development and commercialization." (Annual Report for 2022, Form 10-K, filed March 9, 2023.)

35. While the Company "perform[s] the majority of the manufacturing," it sometimes "use[s] a hybrid approach to manufacturing … whereby certain elements of our

product candidates are manufactured and tested on an outsourced basis at [qualified third-party contract manufacturing organizations] CMOs," but the Company assured investors that "***all [are] designed in compliance with cGMP***." (Annual Report for 2022, Form 10-K, filed March 9, 2023.) Indeed, even under that "previous" "hybrid product supply approach" whereby "certain elements of our product candidates were manufactured internally at our manufacturing facilities in Pleasanton, California, and other elements were manufactured at qualified third-party contract manufacturing organizations (CMOs)," Gritstone assured that "***[a]ll internal and third-party contract manufacturing is performed under cGMP or similar guidelines***." (Annual Report for 2022, Form 10-K, filed March 9, 2023.) But in any event, recently the Company, "has since internalized most of the manufacturing steps to optimize cost and production time and establish full control over … product quality." (Annual Report for 2022, Form 10-K, filed March 9, 2023.)

D. Gritstone Secures Government BARDA Contract To Fund The CORAL Program's Phase 2 Study.

36. Because Gritstone has no commercial-stage products, the "vast majority of" its vaccine programs are "being funded via external collaborators," such as through nonprofits and government grants. (Press Release, May 11, 2023.) In other words, "[t]o date, [the Company] ha[s] not generated any revenue from product sales, and we do not expect to generate any revenue from product sales for the foreseeable future," with all recognized gains flowing from those prior agreements. (Q1 Quarterly Report, Form 10-Q, filed May 11, 2023.)

37. The Company also had taken on significant debt in its operations. In the Company's May 11, 2023, 10-Q, Gritstone elaborated that, "[a]s of March 31, 2023, we had cash, cash equivalents, and marketable securities of $145.8 million and an accumulated deficit of $555.1 million." (Q1 Quarterly Report, Form 10-Q, filed May 11, 2023.) However, at that

time, the Company "expect[s] that our cash, cash equivalents, and marketable securities as of March 31, 2023 will enable us to fund our current and planned operating expenses and capital expenditures for at least the next 12 months." (Q1 Quarterly Report, Form 10-Q, filed May 11, 2023.) Under its "risk factors," it noted, "[h]owever, … [the Company] may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations." (Q1 Quarterly Report, Form 10-Q, filed May 11, 2023.)

38. Those cash issues came to a head a few months later, in August 2023, when the Company filed its 10-Q, with a new "going concern" warning, flagging that "[t]he Company's cash, cash equivalents and marketable securities ***are not sufficient*** to fund the Company's planned operations for a period of 12 months." (Q2 Quarterly Report, Form 10-Q, filed August 9, 2023.) Gritstone noted "we have incurred significant losses and negative cash flows," have "an accumulated deficit of $590.3 million as of June 30, 2023," and "expect to incur substantial additional losses in the future as we conduct and expand our research and development activities," and that "[t]hese conditions raise substantial doubt about our ability to continue as a going concern for a period of one year." (Q2 Quarterly Report, Form 10-Q, filed August 9, 2023.) As such, for "future funding requirements," the Company noted it "anticipat[es] that we will need substantial additional funding in connection with our continuing operations." (Q2 Quarterly Report, Form 10-Q, filed August 9, 2023.)

39. A few weeks after issuing this "going concern" warning, Gritstone's government-funded contract award appeared to solve the Company's cash crisis. On September 27, 2023, Gritstone announced that it entered into a contract (the "BARDA Contract" or "Contract") with the Biomedical Advanced Research and Development

Authority ("BARDA"), a component of the Administration for Strategic Preparedness and Response in the U.S. Department of Health and Human Services ("HHS"). Under the BARDA Contract, the Company "***will receive funding of up to an estimated $433 million*** to conduct a 10,000 participant randomized Phase 2b comparative study evaluating the Company's next-generation self-amplifying mRNA vaccine candidate … to protect against COVID-19." (Form 8-K, filed Sept. 27, 2023.)

40. In a press release announcing this collaboration, Defendant Allen touted that "[w]e are honored to receive this award from BARDA to advance our next-generation samRNA vaccine against COVID-19 … which provides strong validation of our innovative vaccine platform in infectious diseases." (Press Release, Sept. 27, 2023.) Not only does this Contract "supply the necessary resources to advance the development of CORAL," but it also "signifies the trust and confidence the U.S. government has placed in our novel vaccine approach.'" (Press Release, Sept. 27, 2023.) Indeed, while "'[f]irst-generation COVID-19 vaccines provided great utility during the height of the pandemic," but were "limited in breadth and durability of clinical protection,'" and "'CORAL was designed to address these limitations by inducing durable neutralizing antibody and T cell-based immunity against current and future SARS-CoV-2 variants.'" (Press Release, Sept. 27, 2023.) "'Across multiple Phase 1 studies, our samRNA vaccine … has demonstrated induction of potent immune responses with potential to drive broad and durable clinical protection – this potential will now be tested in a randomized setting'" for Phase 2, and "'[w]e are excited about this opportunity to work alongside BARDA and look forward to initiating the Phase 2b study … in the first quarter of 2024.'" (Press Release, Sept. 27, 2023.) "Preparations for the study are underway, and execution of the study will be fully funded by BARDA." (Press Release, Sept.

27, 2023.) Given this influx of a runway of secured cash, "[t]he Company estimates that, based on the fees payable and anticipated reimbursement of certain expenses to the Company under the BARDA Contract, the Company's ***cash runway will be extended into the fourth quarter of 2024***." (Form 8-K, filed Sept. 27, 2023.)

41. To access this significant cash influx, the Company must first fulfill the Contract's "base period" requirements. Under the Contract, the base period required Company to "perform[] … certain milestones such as preparation of protocol synopsis and submission of an investigational new drug application" approved by the FDA. (Form 8-K, filed Sept. 27, 2023.) The Contract provided $10 million to the Company to fulfill these requirements during the "base period of performance" by the end of Q1, from September 30, 2023, to March 31, 2024. (BARDA Contract.) After "[f]ollowing successful completion of the base period," fulfilling those milestones, the Company would initiate the CORAL Phase 2 study in Q1 2024 and receive the "***approximately $423 million of additional BARDA funding*** … in support of the clinical trial execution and additional analyses for the clinical trial." (Form 8-K, filed Sept. 27, 2023.) The Contract expressly provided that ***"[t]he Contractor's success in completing the required tasks under the work segments [base period] must be demonstrated***" and "will constitute the basis for the decision to exercise any follow-on option period(s)" for this massive funding of this Phase 2 trial. (BARDA Contract.)

42. Critically—in conformance with the FDA's regulations—the Contract expressly required Gritstone to use cGMP standards. Under the section detailing the required "Manufacturing Standards" to be used throughout the study, the Contract stated: "***The Good Manufacturing Practice Regulations (GMP) will be the standard to be applied for clinical manufacturing, processing, packaging, storage, and delivery of this product***." (BARDA

Contract.) The Contract is subject to cancellation if the FDA identifies a "material failure" to comply with cGMP (i.e., one affecting the safety, purity, or potency of the product) and the Company fails to resolve the problem within a certain period (the specific timeframe is redacted in the version posted to the SEC website). (BARDA Contract.)

43. Following this win for the Company, over the next few months, Defendants repeatedly lauded this partnership and the anticipated study commencement after fulfilling the base period requirements in Q1. In an October 2023 press release, Defendants conveyed that "[p]reparations for the BARDA-funded, 10,000 subject Phase 2b, head-to-head study are underway, having entered the base period, and we look forward to initiating the study in the first quarter of 2024." (Press Release, Oct. 11, 2023.) And in a November 2023 press release, Defendants reiterated that "[p]er the [BARDA] contract, which is valued at up to $433.0 million, Gritstone is currently preparing to conduct a 10,000 participant, randomized Phase 2b double-blinded study to compare the efficacy, safety, and immunogenicity of Gritstone's samRNA vaccine candidate against an approved COVID-19 vaccine," again teasing that "[p]reparations for the study are covered under the initial base period of the contract," and "Gritstone expects the [Phase 2] study to be initiated in the first quarter of 2024" after the base period concludes. (Press Release, Nov. 8, 2023.)

E. Unknown to Investors, Gritstone Did Not Have The Necessary cGMP Manufacturing Capabilities and Materials to Comply With The BARDA Contract.

44. Contrary to Gritstone's rosy statements assuring investors about the Company's robust cGMP manufacturing and processing capabilities, the Company was scrambling to procure the necessary cGMP materials for the CORAL Phase 2 vaccine program—even well before the Company announced the BARDA Contract.

45. Behind the scenes, a confidential witness ("CW1" or "Director of Quality Assurance") conveyed this true, dismal state of Gritstone's actual cGMP manufacturing processes. CW1 was the Director of Quality Assurance at Gritstone from March 2023 to February 2024. In this role, CW1 was responsible for ensuring the quality standards of the Company's drug products and worked on an internal task force focused on finding all GMP-grade raw materials from vendors for manufacturing the COVID-19 vaccine for the CORAL Phase2b study. CW1 was based at the Company's manufacturing facility in Pleasanton, CA, and reported Karen Trujillo, Senior Director of Quality Control and Analytical Technologies, and Trujillo reported to Luis Cabassa-Latoni, the Vice President of Quality.

46. CW1 revealed that—when CW1 joined Gritstone in March 2023—the Company already had been aware of, and had been struggling to fix, Gritstone's lack of cGMP capabilities to launch the CORAL Phase 2 study. In particular, Gritstone had already recognized that many of the raw materials used to manufacture its COVID-19 CORAL vaccine were non-cGMP-grade. The Company had already initiated "heavy discussions" about the need to find all GMP-grade raw materials for the manufacturing of the Company's COVID-19 vaccine. Before CW1 joined, "[t]he Company did recognize," this huge problem: "By the time I started, it was already being discussed" on how to "look at our manufacturing process and evaluate how many raw materials were cGMP vs non-GMP'" and how to procure the needed cGMP components.

47. Those discussions revealed that the Company had been aware that many of the raw materials used to manufacture the CORAL vaccine were not cGMP-grade—a huge issue given that the FDA requires all Phase 2 trials be conducted using cGMP materials. Indeed, before CW1 joined in March 2023, the Company had already put together a "long list" of raw

materials that were being used to make the vaccine that were non-GMP-grade and that needed replacement. In addition, by the time CW started at Gritstone in March 2023, the Company had already formed a "task force" with the express goal of procuring those cGMP-grade raw materials to replace the non-GMP-grade raw materials used for making the vaccine that would be used in the CORAL Phase2b trial. "There was a huge task force for it," CW said. "That was a huge project to put together."

48. When CW1 joined Gritstone, CW1 became a member of the cGMP task force. This task force included employees from the manufacturing, supply chain, and regulatory departments, and CW1 hired a full-time raw material quality employee to assist with their efforts. CW1 said the team was working with the Company's existing vendors of non-GMP-grade raw materials to inquire if the vendors could start providing cGMP-grade raw materials. "There were discussions about how we can make it to the Q1 [BARDA Phase 2 CORAL] trial," CW1 said. "The discussions were very, very heavy … what is it we could do" to comply with the BARDA Contract.

49. By the end of 2023—while the Company had found some sources of cGMP-grade materials to replace the non-GMP materials—Gritstone was still missing "critical" cGMP materials needed for the Phase 2 CORAL study. Of those materials that the Company could not find replacements, "[s]ome, we would not be able to get," and even some "we did not know where to get the cGMP-grade" quality. Indeed, CW1 conveyed that "some of the materials they could not find at cGMP-grade were unique for Gritstone's vaccine," "while others were materials in low demand and/or supplied by small vendors." CW1 also stated that "some of those small vendors were unable to implement the Good Manufacturing Practices needed to meet cGMP-grade requirements."

50. CW1 confirms that management was well aware of these cGMP failures. CW1 conveyed that the Chief Operating Officer (COO) Erin Jones regularly "informed CEO Andrew Allen about the status of the task force's work, including details about the inability to acquire GMP-grade raw materials by early 2024" to comply with the BARDA Contract's timeline and launch the Phase 2 trial. CW1 also participated in meetings with the task force and COO Jones throughout 2023, "during which status of the efforts to procure GMP-grade materials was discussed" and conveyed to other upper management, including the CEO. CW1 had personal "conversations with COO Jones about the status of the procurement efforts," and conveyed how COO Jones "was informed at every step about which GMP-grade raw materials were procured and which of the raw materials had not yet been procured at GMP-grade." CW also revealed how "during the meetings and conversations with COO Jones," Jones "conveyed that he was reporting all the information to CEO Andrew Allen": "He [the COO] was reporting to the CEO," CW1 said, and "[w]e discussed how to convey the information to the CEO …. One hundred percent this [was] be[ing] conveyed to the CEO."

51. This massive failure of the Company's cGMP processes for the CORAL vaccine program is unsurprising given, as reported by another confidential witness ("CW2"), the Company's infectious disease program was chronically under-resourced.

52. CW2 was the Senior Vice President of Clinical Development for Infectious Diseases at Gritstone from July 2022 to August 2023. CW2 reported to Karin Jooss, Ph.D., Execuitve Vice President of Research and Development and Chief Scientific Officer, who reported to Defendant CEO Allen. CW2 also sometimes reported directly to Defendant CEO Allen. CW2's job involved advising Company leadership and assisting with the process of developing clinical vaccines for infectious diseases. CW2 has "25 years of experience

working in clinical trials for infectious diseases" and was "one of two physicians in executive positions at Gritstone (CEO Andrew Allen was the other), and the only physician in an executive position with expertise in infectious disease."

53. CW2 conveyed that Gritstone "was focused on its oncology treatments and did not provide enough resources for its infectious disease team," including the CORAL program. CW2 expressly "advised [Jooss] and [Defendant CEO] Allen that the company should hire more infectious disease experts for its under-supported infectious disease team." As CW2 stated: "If the Company would like to support their investment in infectious disease and develop an infectious disease vaccine, they need to build to a critical mass around infectious disease into the Company." That did not happen: instead of CW2's team increasing, CW2's "team shrunk as employees on his team began to quit due to what [CW2] described as a toxic work environment." In August 2023, CW2 also quit, a large reason due to "work demands" that CW2 "felt were unreasonable considering [CW2's] lack of staff." Given Gritstone's stronger "focus on oncology," CW2 said, "[i]nfectious disease was always left to second place," and "I would not be surprised if they [management] overlooked the need for GMP-grade materials for an infectious disease program."

54. Yet another CW ("CW3") elaborated on the massive hurdles this CORAL vaccine project posed to the Company. CW3 worked for Gritstone from January 2020 to August 2024 as an Associate Vice President of Process Development (March 2024 – August 2024) and then as a Senior Director of Process Development (January 2020 – March 2024). In that role, CW3 was responsible for developing the early steps of making the COVID-19 vaccine, which is the "drug substance" stage (also referred to as the "upstream" process), and it is the stage where the active ingredient (the mRNA) is made. Once CW3 completes the

development of the drug substance phase, those guidelines are handed off to the manufacturing team to follow when making the vaccine. CW3 reported to Vijay Yabannavar, Executive Vice President of Chief Manufacturing and Tech Ops Officer and Chief Technical Development Officer.

55. According to CW3, "there are a hundred-plus raw materials used in the upstream process for Gritstone's COVID-19 vaccine." These "raw materials are used and combined to make buffers, media, regents, and other products that are then used to make the vaccine." When asked about Defendant CEO Allen's involvement and knowledge of communications with the FDA regarding using of GMP-grade vs non-GMP-grade raw materials, CW3 conveyed "He [Allen] was aware of the entire communication. Nothing goes without his knowledge."

56. Despite these massive shortcoming (and the material impact on the Company's operations), Gritstone never conveyed these cGMP manufacturing and sourcing problems in any of its public statements or risk disclosures.

F. Given These Known cGMP Failures, Defendants Knew That They Could Not Comply With The BARDA Contract.

57. Plaintiffs retained pharmaceutical expert Todd Clark to assess Defendants' statements regarding the CORAL vaccine program. Mr. Clark has a Master of Science degree in drug development and regulation from Johns Hopkins University and an MBA from the Kellogg School of Business at Northwestern University. He is a pharmaceutical expert with approximately thirty years of experience consulting for branded and generic drug companies, as well as biotech firms, investment banks, and health technology services to advise them on, among other things, drug development and clinical trial design. Mr. Clark has consulted with many of the top pharmaceutical companies in the world, has published extensively on industry

topics, including clinical trial issues, and is frequently quoted in trade journals and by academics, and he has testified in numerous cases as an expert on pharmaceutical matters.

58. Based on his assessment of the timeline and CW1's statements, when Gritstone announced the BARDA contract in September of 2023, given the known lack of cGMP materials available throughout 2023, Mr. Clark concludes that it was "nearly certain that the Company knew it could not meet a Q1 2024 trial start given that, for at least the previous six months, it had been unable to secure necessary cGMP-grade raw materials to fulfill needs that were a fraction of what was required under the BARDA Contract." When the Company announced the Contract award in late September 2023, it had mere months to resolve this problem and scale up to meet the increased demand for cGMP-grade materials so that it could begin the Phase 2 trial in 1Q 2024. Confidential witnesses confirmed that the Company has "no answer for this problem throughout 2023," including up to and until this September 27, 2023 announcement, and "solving this issue in a few months was not feasible." In Mr. Clark's assessment, "because the BARDA contract exacerbated an already unresolved need for cGMP materials many times over, it is difficult to imagine how Gritstone perceived that there could be a realistic solution within the stated timeframe." And, "at the bare minimum, the Company should have disclosed the cGMP problems and acknowledged the probability of delay."

59. In particular, Mr. Clark explained that the BARDA-funded Phase 2 study—with anticipated enrollment of 10,000 subjects—represented a "massive increase over the Phase 1 studies that Gritstone had conducted for the COVID vaccine previously." Across the three previous Phase I trials, "there were a total of 463 patients or less than 5% of the number that would be included in the BARDA trial." Based on the "material differences" between

the Phase I Coral study and this new BARDA-sponsored Phase 2 of 10,000 subjects, it was "unreasonable for Gritstone to say it could comply with this Contract and cGMP requirements given the far greater supply challenge this posed." According to Mr. Clark, the raw materials used for vaccines "are specialized and complicated to produce, with the result that supply constraints and high costs are frequently encountered." Indeed, Gritstone had already run into these problems and had been making substantial efforts to resolve them without success.

60. As Mr. Clark elaborated, "regulatory agencies view raw materials as critical inputs" and the raw materials used for vaccines "are specialized and complicated to produce, with the result that it is common to experience supply constraints and high costs." Compliance with cGMP is especially important for vaccines as they are immune-triggering agents and may therefore carry safety risks that may not be present with other products. The need for strictly controlled inputs is "further heightened when the vaccine is delivered by injection," and Gritstone's "COVID vaccine was injected intramuscularly."

61. In addition, Gritstone's use of samRNA would also alert the Company to the importance of using cGMP materials and the challenges this task posed. The process for production of samRNA vaccines (Gritstone's approach) has similarities with the production process for mRNA vaccines. It has been recognized that "[t]he shortest path to mRNA therapeutic success starts with high quality raw materials," and "[u]sing raw materials that are antibiotics-free and animal-origin-free is a crucial biopharmaceutical requirement to limit the risk of allergic reactions and viral contamination."

62. According to Mr. Clark, the FDA would have communicated the need to use cGMP materials when reviewing the Company's protocol and design for the CORAL program. Notably, Gritstone's 10-K filed March 2023 acknowledges that "grade of

materials" was one of the subjects discussed in its pre-IND meeting with the FDA. This is unsurprising, and it clearly demonstrates that the FDA evaluates the quality of raw materials even at any early stage in the clinical development process. While Gritstone might have obtained a cGMP exception under the 2006 Final Rule covering Phase 1 research, that exception does not apply to Phase 2 or later clinical studies. As such, the only reasonable expectation going forward was that the FDA would require use of cGMP raw materials which is, after all, the standard that is demanded by both the BARDA Contract and longstanding FDA regulations. In Mr. Clark's assessment, the Company would have no basis to expect the FDA to grant a waiver of these cGMP requirements.

63. Further, and of considerable importance, the record shows that there should not have been any remaining doubt on this point by December 2023 because, as Gritstone acknowledged in its 2024 Annual Report, it submitted an IND for the Phase 2b CORAL Study (*i.e.*, the BARDA-funded trial) in November 2023, the FDA informed the Company that the trial could not proceed in December 2023, and the FDA issued a formal clinical hold letter reiterating that position in January 2024. Consistent with FDA policy, the letter stated that Gritstone would "be required to use GMP-grade materials in the manufacture of the vaccine" for the Phase 2b trial.

64. Although Gritstone did not disclose the details of the December 2023 communication, CFR 312.42(d) states that the FDA may implement a clinical hold "by telephone or other means of rapid communication or in writing" and, that when it does so, the "clinical hold order will identify the studies under the IND to which the hold applies, *and will briefly explain the basis for the action*." Further, as "soon as possible, and no more than 30 days after imposition of the clinical hold, the Division Director will provide the sponsor a

written explanation of the basis for the hold." In other words, the Code of Federal Regulations requires the FDA to communicate the basis for the hold as part of the initial notification. As such, Gritstone would have been aware that the trial could not proceed without cGMP-grade materials no later than the December 2023 date that the Company was first informed of the clinical hold. But according to Mr. Clark, the outcome should have been clear well before December 2023 given the FDA's requirements that all Phase 2 studies comply with cGMP and the Company's inability to address its lack of critical cGMP materials over the course of the preceding year.

V. MATERIALLY FALSE AND MISLEADING STATEMENTS ISSUED DURING THE CLASS PERIOD

65. Despite the significant cGMP failings known to Gritstone, Defendants made numerous false and misleading statements during the Class Period about its manufacturing strategies and capabilities. Plaintiffs assert that all statements set forth below that are bolded and italicized are materially false and misleading for the reasons set forth therein.

66. The Class Period begins on March 9, 2023, when Gritstone filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operational results for the year ended December 31, 2022. In providing an overview of the Company, the 2022 10-K touted that cGMP manufacturing was one of its core competencies, stating in relevant part:

> We believe the speed, quality, reliability, and scalability of our manufacturing capabilities is a core competitive advantage to our clinical development and potential commercial success. ***We have successfully internalized all biomanufacturing steps to drive down both cost and production time, as well as establish full control over intellectual property and product quality.*** We have internalized the majority of our quality control testing elements as well, though we outsource where prudent and feasible. We believe that operating our own manufacturing facility provides us with enhanced control of material supply for both clinical trials and the

> commercial market, will enable the more rapid implementation of process changes, and will allow for better long-term manufacturing cost control. We have the capability to manufacture every element involved in clinical development of our oncology vaccine-based immunotherapies.
> …
> **In-house GMP Manufacturing**
> ***We manufacture our products at our own fully-integrated good manufacturing practice (GMP) biomanufacturing facilities. Our ability to control the manufacturing of high-quality vaccine products, and scale production, if early data are positive, is critical for efficient clinical development and commercialization.*** We have invested significant resources in our Cambridge, Massachusetts sequencing lab and our Pleasanton, California biomanufacturing facility to address these needs and position ourselves to control the critical steps in the production of our immunotherapy candidates.
> …
> Our goal is to carefully manage our fixed-cost structure, maximize optionality, and drive long-term cost of goods as low as possible. We have used a hybrid approach to manufacturing and release of our individualized immunotherapy candidates whereby certain elements of our product candidates are manufactured and tested on an ***outsourced basis at CMOs***, ***and other elements of our product candidates*** are manufactured and released internally at the 42,600 square foot manufacturing facility we established in 2017 in Pleasanton, California, ***all designed in compliance with cGMP***.

67. In addition, in discussing the Company's CORAL Development Program, and "Our Interactions with the Regulatory Health Authorities," the 2022 10-K stated, in relevant part:

> A pre-IND interaction with the FDA was conducted to review the proposed clinical investigation of ChAd vectors encoding the SARS-CoV-2 and CD8+ T-cell epitope spike antigen sequences in normal healthy subjects. ***The FDA concluded that the overall manufacturing and release testing for the CORAL vaccines candidates, which is similar to the GRANITE/SLATE process, appeared acceptable and requested detail on the transfection process, grade of materials, and release tests be submitted in the IND***. We also received feedback that pre-clinical pharmacokinetic, and toxicology studies conducted in support of the GRANITE IND could be used to support the safety information needed to initiate the SARS-CoV-2 clinical study, and that additional animal immune response pharmacodynamic data would be submitted within the IND. ***The FDA previewed the proposed clinical protocol, confirmed that the overall design appeared reasonable*** and requested we include language to clarify dose escalation, stopping rules and

> a sentinel arm. The FDA requested that we exclude those subjects who are being treated with COVID-19 investigational agents or who have a high risk of potential exposure to SARS-CoV-2.

68. In discussing potential "risk factors," outlined certain risks which could adversely impact Gritstone's business, financial condition, results of operations, or prospects if they came to pass, including the following the Company stated:

> ***We currently perform the majority of the manufacturing of our product candidates internally and rely on qualified third parties to supply some components of our product candidates. Our inability to manufacture sufficient quantities of GRANITE, SLATE or any other current or future product candidates, or the loss of our third-party suppliers, or our or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially adversely affect our business***.
>
> Manufacturing is a vital component of our immunotherapy approach, and we have invested significantly in our manufacturing facility. To ensure timely and consistent product supply assurance to our patients, we previously used a hybrid product supply approach whereby certain elements of our product candidates were manufactured internally at our manufacturing facilities in Pleasanton, California, and other elements were manufactured at qualified third-party contract manufacturing organizations (CMOs). ***All internal and third-party contract manufacturing is performed under cGMP or similar guidelines***. We have since internalized most of the manufacturing steps to optimize cost and production time and establish full control over intellectual property and product quality. We will need to continue to scale up our manufacturing operations, as we continue to build the infrastructure and improve the capability internally to manufacture all supplies needed for our product candidates or the materials necessary to produce them for use in the conduct of our preclinical studies or clinical trials. We currently lack the internal resources and the capability to manufacture certain elements of our product candidates on a late-clinical or commercial scale. Accordingly, we have made, and will be required to continue to make, significant investments in our manufacturing facility and processing in the future, and our efforts to scale our manufacturing operations may not succeed.

69. The statements identified in bold and italicized text in the paragraphs above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as more fully described above, Gritstone

failed to disclose that (1) the company had not internalized all manufacturing steps to ensure product quality and the required cGMP of its CORAL vaccine candidates; (2) Gritstone's internal and third-party contract manufacturing was not all performed under cGMP; (3) Gritstone currently did not have the necessary cGMP materials to manufacture and process the vaccine components in the CORAL vaccine study; (4) not all "third-party contract manufacturing is performed under cGMP or similar guidelines" given some of Gritstone's vendors were not cGMP compliant; and (5) the risks posed by a failure to procure the necessary cGMP grade materials at its vendor sites was not merely hypothetical.

70. Appended to the 2022 10-K as an exhibit was a signed certification pursuant to the Sarbanes-Oxley Act of 2002 by the Individual Defendants, attesting that "[t]he information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company."

71. On May 11, 2023, Gritstone hosted an earnings call with investors and analysts to discuss the Company's Q1 2023 results (the "Q1 2023 Earnings Call"). During the scripted portion of the Q1 2023 Earnings Call, Defendant Allen stated, in relevant part:

> ***We look forward to continuing to work with collaborators to demonstrate the full potential of our samRNA platform against both SARS-CoV-2 and other important viruses. We expect to share additional data from our CORAL program this fall.*** And these data will relate to different immunogen designs, illustrating the flexibility of the platform to accommodate both B Cell and T cell epitopes in efficient formats. It is clear that there is still need for next generation solutions against COVID-19 and the recent actions by the White House and BARDA are encouraging signals that the pursuit of enhanced breadth and durability of protection is not going to the wayside. Outside of our PCV and SARS-CoV-2 programs, our forward looking efforts to identify and develop potentially transformative vaccines continues….
>
> So as described today, happily Gritstone is in a period of significant momentum …. Within infectious disease, we're pioneering a novel technology that could represent the next RNA platform approach against

> SARS-CoV-2 and beyond. We look forward to continuing to share our findings with you as progress continues.

72. The statements identified in bold and italicized text in the paragraphs above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as more fully described above, Gritstone failed to disclose that Gritstone currently did not have the necessary cGMP materials to manufacture and process the vaccine components in the CORAL vaccine study.

73. In the May 11, 2023 10-Q, the quarterly report also noted "there have been no material changes to the risk factors set forth in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 9, 2023," including the risk factors posing that "[a]ll internal and third-party contract manufacturing is performed under cGMP or similar guidelines."

74. The May 10-Q also related risks that the Company "will require substantial additional financing to achieve our goals, and a failure to obtain such necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations," listing:

> ***Our future capital requirements depend on many factors, including:***
> ***-the scope, progress, results and costs of developing each of our product candidates, including conducting preclinical studies and clinical trials, either on our own or in collaboration with others;***
> ***-potential delays in our ongoing clinical trials, including for reasons beyond our control***;

75. The statements identified in bold and italicized text in the paragraphs above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as more fully described above, Gritstone failed to disclose that (1) Gritstone currently did not have the necessary cGMP materials to

manufacture and process the vaccine components in the CORAL vaccine study; and (2) the risks posed by a failure to procure the necessary cGMP grade materials at its vendor sites (and thus the financial burdens imposed by delay) was not merely hypothetical.

76. Appended to the May 11, 2023 10-Q as an exhibit was a signed certification pursuant to the Sarbanes-Oxley Act of 2002 by the Individual Defendants, attesting that "[t]he information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company."

77. On August 9, 2023, Gritstone issued a press release announcing the Company's Q2 2023 financial results. The press release quoted Defendant Allen as stating, in relevant part:

> ***The promising data we continue to see from our CORAL (SARS-CoV-2 vaccine) program*** highlights the differentiation and potential advantages of self-amplifying mRNA (samRNA) over current vaccines against infectious diseases. ***Our recent publication in Nature Communications demonstrates the scientific rigor of our work to date and the ability of our samRNA platform to drive potent and durable immune responses***. We believe our samRNA vaccine candidates have demonstrated strong potential to serve as next-generation vaccine solutions to COVID-19 and other infectious diseases.

78. The statements identified in bold and italicized text in the paragraphs above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as more fully described above, Gritstone failed to disclose that Gritstone currently did not have the necessary cGMP materials to manufacture and process the vaccine components in the CORAL vaccine study.

79. In the August 9, 2023 Form 10-Q, the quarterly report also noted "there have been no material changes to the risk factors set forth in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 9, 2023,"

including the risk factors posing that "[a]ll internal and third-party contract manufacturing is performed under cGMP or similar guidelines."

80. Appended to the May 11, 2023 10-Q as an exhibit was a signed certification pursuant to the Sarbanes-Oxley Act of 2002 by the Individual Defendants, attesting that "[t]he information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company."

81. On September 27, 2023, Gritstone issued an 8-K under Item 1.01 "Entry into a Material Definitive Agreement," announcing it was awarded the BARDA Contract:

> On September 27, 2023, Gritstone bio, Inc. (the "Company") entered into a contract (the "BARDA Contract") with the Biomedical Advanced Research and Development Authority ("BARDA"), a component of the Administration for Strategic Preparedness and Response in the U.S. Department of Health and Human Services. ***Under the BARDA Contract, the Company will receive funding of up to an estimated $433 million to conduct a 10,000 participant randomized Phase 2b comparative study evaluating the Company's next-generation self-amplifying mRNA vaccine candidate containing Spike plus other viral targets to protect against COVID-19***.
>
> The BARDA Contract could result in payments to the Company of up to approximately $433 million. The BARDA Contract consists of a base period (ending on or before the first quarter of 2024) and a total contract period-of-performance (base period plus two stages gated at BARDA's discretion) of up to approximately four years. The base period for the BARDA Contract includes government funding of up to approximately $10 million for performance of certain milestones such as preparation of protocol synopsis and submission of an investigational new drug application. ***Following successful completion of the base period, the BARDA Contract provides for approximately $423 million of additional BARDA funding for two stages gated at BARDA's discretion in support of the clinical trial execution and additional analyses for the clinical trial***.
>
> The BARDA Contract contains terms and conditions that are customary for contracts with BARDA of this nature, including provisions giving the government the right to terminate the contract at any time for its convenience.

> ***The Company estimates that, based on the fees payable and anticipated reimbursement of certain expenses to the Company under the BARDA Contract, the Company's cash runway will be extended into the fourth quarter of 2024***.

82. The statements identified in bold and italicized text in the paragraphs above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as more fully described above, Gritstone failed to disclose that: (1) Gritstone currently did not have the necessary cGMP materials to manufacture and process the vaccine components in the CORAL vaccine study, and knew it would not be able to procure those materials in time to meet the base period requirements; and (2) this known failure to meet the contract's cGMP requirements would delay or cancel the contract, and certainly would not provide the Company with the needed cash runway in Q1 2024.

83. On September 27, 2023, Gritstone issued a press release entitled "Gritstone bio Awarded BARDA Contract to Conduct Comparative Phase 2b Study Evaluating Next-Generation Vaccine Candidate for COVID-19 Valued at up to $433 Million." The press release stated, in relevant part:

> Gritstone … announced today that it was awarded a contract by the Biomedical Advanced Research and Development Authority (BARDA) to conduct a Phase 2b comparative study evaluating Gritstone's self-amplifying mRNA (samRNA) vaccine candidate containing Spike plus other viral targets to protect against COVID-19. ***The agreement, which is valued at up to $433 million, was awarded as part of 'Project NextGen,' an initiative by the U.S. Department of Health and Human Services (HHS) to advance a pipeline of new, innovative vaccines and therapeutics providing broader and more durable protection for COVID-19***.
>
> ***Under the contract, Gritstone bio will conduct a 10,000 participant, randomized Phase 2b double-blinded study to compare the efficacy, safety, and immunogenicity of the Gritstone next-generation COVID-19 vaccine candidate with an approved COVID-19 vaccine. Preparations for the study are underway, and execution of the study will be fully funded by BARDA***.

> Gritstone will run the study in the United States in collaboration with the COVID-19 Prevention Network (CoVPN), a NIAID-supported network of clinical trial sites based at Fred Hutchinson Cancer Center with experience conducting large COVID-19 vaccine trials.
>
> "We are honored to receive this award from BARDA to advance our next-generation samRNA vaccine against COVID-19 (the CORAL program), which provides strong validation of our innovative vaccine platform in infectious diseases. ***Not only does this contract supply the necessary resources to advance the development of CORAL, but it also signifies the trust and confidence the U.S. government has placed in our novel vaccine approach***," said [Defendant] Allen[.] "…Across multiple Phase 1 studies, our samRNA vaccine … has demonstrated induction of potent immune responses with potential to drive broad and durable clinical protection – this potential will now be tested in a randomized setting. ***We are excited about this opportunity to work alongside BARDA and look forward to initiating the Phase 2b study (CORAL-BARDA) in the first quarter of 2024***. With CORAL moving into a randomized Phase 2 study alongside our personalized cancer vaccine program (GRANITE), Gritstone now sits at the precipice of unlocking the full potential of our novel vaccine platforms in both oncology and infectious diseases."
>
> ….***The CORAL program is supported by Biomedical Advanced Research and Development Authority (BARDA),*** NIAID, the Coalition for Epidemic Preparedness Innovations (CEPI) and the Bill & Melinda Gates Foundation.

84. The statements identified in bold and italicized text in the paragraphs above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as more fully described above, Gritstone failed to disclose that: (1) Gritstone currently did not have the necessary cGMP materials to manufacture and process the vaccine components in the CORAL vaccine study, and knew it would not be able to procure those materials in time to meet the base period requirements; and (2) this known failure to meet the contract's cGMP requirements would delay or cancel the contract, and certainly would not provide the Company with the needed funding in Q1 2024.

85. On October 11, 2023, Gritstone issued a press release entitled "Presentations at IDWeek 2023 Highlight Potentially Differentiated Immunogenicity of Gritstone bio's Next Generation COVID-19 Vaccine." The press stated, in relevant part:

> "The findings presented at IDWeek highlight the potential of our self-amplifying mRNA vaccine to address the limitations of today's approved vaccines against COVID-19 and provide additional clinical rationale for our novel 'spike-plus' approach as we advance into a large head-to-head study," said [Defendant] Allen[.] "These data reaffirm previous findings that our samRNA vaccines have the potential to drive highly durable antibody responses, to enhance immunity through broader T cell responses, and to accomplish this at RNA doses as low as 3 micrograms, one tenth the dose of currently approved mRNA vaccines for COVID-19. The collective data showing that elicited neutralizing antibody titers persist at high levels for at least 12 months – data shared for the first time during IDWeek 2023 – are particularly exciting and further validate the rapid ongoing advancement of the CORAL program. ***Preparations for the BARDA-funded, 10,000 subject Phase 2b, head-to-head study are underway, having entered the base period, and we look forward to initiating the study in the first quarter of 2024***."

86. The statements identified in bold and italicized text in the paragraphs above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as more fully described above, Gritstone failed to disclose that: (1) Gritstone currently did not have the necessary cGMP materials to manufacture and process the vaccine components in the CORAL vaccine study, and knew it would not be able to procure those materials in time to meet the base period requirements; and (2) this known failure to meet the contract's cGMP requirements would delay or cancel the contract, and certainly would not provide the Company with the needed cash runway in Q1 2024.

87. On November 8, 2023, Gritstone issued a press release announcing the Company's Q3 2023 financial results. The press release stated, in relevant part:

> ***In September 2023, Gritstone was awarded a contract by BARDA (the Biomedical Advanced Research and Development Authority), part of the Administration for Strategic Preparedness and Response in the U.S. Department of Health and Human Services, to conduct a Phase 2b comparative study evaluating its next-generation vaccine candidate against COVID-19[.]***
>
> ***(a)This project has been supported in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract number 75A50123C00062.***
>
> ***Per the contract, which is valued at up to $433.0 million, Gritstone is currently preparing to conduct a 10,000 participant, randomized Phase 2b double-blinded study to compare the efficacy, safety, and immunogenicity of Gritstone's samRNA vaccine candidate against an approved COVID-19 vaccine. Preparations for the study are covered under the initial base period of the contract. Gritstone expects the study to be initiated in the first quarter of 2024***.

88. The statements identified in bold and italicized text in the paragraphs above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as more fully described above, Gritstone failed to disclose that: (1) Gritstone currently did not have the necessary cGMP materials to manufacture and process the vaccine components in the CORAL vaccine study, and knew it would not be able to procure those materials in time to meet the base period requirements; and (2) this known failure to meet the contract's cGMP requirements would delay or cancel the contract, and certainly would not provide the Company with the needed cash runway in Q1 2024.

89. On November 8, 2023, Gritstone issued its 10-Q, which described the BARDA contract:

> *Biomedical Advanced Research and Development Authority*
>
> In September 2023, the Company entered into a contract (the "BARDA Contract") with the Biomedical Advanced Research and Development Authority, part of the Administration for Strategic Preparedness and

> Response in the U.S. Department of Health and Human Services ("BARDA"). Under the BARDA Contract, the Company may be eligible to receive funding of up to an estimated $433.0 million to conduct a 10,000-participant randomized Phase 2b comparative study evaluating the Company's next-generation self-amplifying mRNA vaccine candidate containing Spike plus other viral targets to protect against COVID-19. The BARDA Contract could result in payments to the Company of up to approximately $433.0 million. The BARDA Contract consists of a base period (ending on or before the first quarter of 2024) and a total contract period-of-performance (base period plus two stages gated at BARDA's discretion) of up to approximately four years. ***The base period for the BARDA Contract includes government funding of up to approximately $ 10.0 million for performance of certain milestones such as preparation of protocol synopsis and submission of an investigational new drug application. Following successful completion of the base period, the BARDA Contract provides for up to approximately $423.0 million of additional BARDA funding for two stages gated at BARDA's discretion in support of the clinical trial execution and additional analyses for the clinical trial.***
>
> The BARDA Contract contains terms and conditions that are customary for contracts with BARDA of this nature, including provisions giving the government the right to terminate the contract at any time for its convenience
>
> The Company did not recognize any revenue under the BARDA Contract for the three and nine months ended September 30, 2023. No amounts have been received under the BARDA Contract as of September 30, 2023.

90. In that November 2, 2023 10-Q, the section "Management's Discussion and Analysis of Financial Condition and Results of Operations," a section within a company's financial report where management provides a narrative explanation of the company's financial performance, including its current financial position, changes in its financial condition, and future outlook, discussed the BARDA Contract:

> *BARDA Contract*
>
> In September 2023, we entered into the BARDA Contract with BARDA. The contract was awarded as part of Project NextGen, an initiative by the U.S. Department of Health and Human Services to advance a pipeline of new, innovative vaccines and therapeutics providing broader and more durable protection for COVID-19.

Under the BARDA contract, which is valued at up to $433.0 million, we are to conduct a 10,000 participant, randomized Phase 2b comparative study to compare the efficacy, safety, and immunogenicity of the Gritstone next-generation COVID-19 vaccine candidate (our samRNA vaccine containing Spike plus other viral targets) with an approved COVID-19 vaccine. The vaccines evaluated in the study are to be tailored to the Omicron XBB.1.5 Spike sequence. ***Preparations for the study are underway, and we expect to initiate the study in the first quarter of 2024.*** Gritstone plans to run the study in the United States in collaboration with the COVID-19 Prevention Network ("CoVPN"), a NIAID-supported network of clinical trial sites based at the Fred Hutchinson Cancer Center that has experience conducting large COVID-19 vaccine trials.

The BARDA Contract consists of a base period (ending on or before the first quarter of 2024) and a total contract period-of-performance (base period plus two stages gated at BARDA's discretion) of up to approximately four years. ***The base period for the BARDA Contract includes government funding of up to $10.0 million for performance of certain milestones such as preparation of protocol synopsis and submission of an investigational new drug application. Following successful completion of the base period, the BARDA Contract provides for up to approximately $423.0 million of additional BARDA funding for the final two stages gated at BARDA's discretion in support of the clinical trial execution and additional analyses for the clinical trial***.

Operating Expenses

……

Our future capital requirements depend on many factors, including:

• ***the scope, progress, results and costs of developing our product candidates, and of conducting preclinical studies and clinical trials, including our clinical trials for GRANITE, SLATE and CORAL***;

• the timing of, and the costs involved in, obtaining regulatory approvals for our oncology and infectious disease immunotherapy product candidates; in particular, any costs incurred in connection with any future regulatory requirements that may be imposed by the FDA or foreign regulatory bodies;

• the number and characteristics of any additional product candidates we develop or acquire;

• the timing and amount of any milestone, royalty or other payments we are required to make pursuant to any current or future collaboration or license agreements;

• the cost of manufacturing our product candidates we successfully commercialize, including the cost of scaling up our internal manufacturing operations;

• the cost of commercialization activities, including building a commercial infrastructure, marketing, sales and distribution costs;

• our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements, and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;

There have been no changes to our critical accounting policies since we filed our Annual Report on Form 10-K for the year ended December 31, 2022 with the SEC on March 9, 2023. For a description of our critical accounting policies, please refer to that Annual Report on Form 10-K.

91. In that November 2, 2023 10-Q, under "risk factors," the Company stated:

ITEM 1A. Risk Factors

There have been no material changes to the risk factors set forth in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 9, 2023, Part II, Item 1A of our Quarterly Report on Form 10-Q for the months ended March 31, 2023 filed with the SEC on May 11, 2023, and Part II, Item 1A of our Quarterly Report on Form 10-Q for the months ended June 30, 2023 filed with the SEC on August 9, 2023, except as set forth below.

A significant portion of the funding for the continued development of our next-generation samRNA vaccine candidate containing Spike plus other viral targets to protect against COVID-19 is currently expected to come from the BARDA Contract, and if BARDA were to decline to pursue any of the gated stages, eliminate, reduce, delay, or object to extensions for funding available to us under the BARDA Contract, this could have a significant, negative impact on our revenues and cash flows, and we may be forced to suspend or terminate the continued development of the product candidate or obtain alternative sources of funding.

We anticipate that a significant portion of the funding for the continued development of our next generation self-amplifying mRNA vaccine candidate containing Spike plus other viral targets to protect against COVID-19 will come from the BARDA Contract. The BARDA Contract provides for funding of up to an estimated $433.0 million to conduct a 10,000 participant randomized Phase 2b comparative study evaluating our self-amplifying RNA vaccine candidate containing Spike plus other viral targets to protect against COVID-19. The base period under the BARDA Contract

includes government funding of only up to approximately $10.0 million for performance of certain milestones such as preparation of protocol synopsis and submission of an investigational new drug application. ***Our ability to receive any of the remaining $423.0 million in additional funding provided for under the BARDA Contract is dependent on BARDA electing to continue to fund additional two gated stages, which it may do or not do at its sole discretion***. The base period for performance under the BARDA Contract runs from September 2023 to March 2024. The option periods for the two additional gated stages run from January 2024 to March 2026 and from July 2024 to July 2026. In addition, BARDA is entitled to terminate the BARDA Contract for convenience at any time, in whole or in part, and is not required to provide continued funding beyond reimbursement of amounts currently incurred and obligated by us as a result of contract performance. ***In addition, activities covered under the base period may ultimately cost more than is covered by the BARDA Contract and may require a longer performance period to complete than is remaining under the terms of the BARDA Contract.*** BARDA is not required to provide funding above the approximately $10.0 million currently obligated for the base period of the BARDA Contract, nor is BARDA required to extend the base period of performance or elect to pursue any of the gated stages. If activities covered under the base period cost us more than the approximately $10.0 million currently obligated for the base period under the BARDA Contract, and we are unable to secure additional funding from BARDA to complete performance of the base period activities, we would have to bear the cost to complete the activities. ***Further, if we are unable to complete the base period activities during the base period due to circumstances that may be either within or outside of our control, including, among others, any potential delays in sourcing an approved comparator vaccine, and BARDA is unwilling to allow for additional time, then BARDA may decide to terminate the BARDA Contract.***

Moreover, the continuation of the BARDA Contract primarily depends on our ability to meet development milestones previously agreed to with BARDA and on our compliance with certain operating procedures and protocols. Further, as an organization, we are relatively new to government contracting and the related regulatory compliance obligations, and are continuing to develop and implement our internal compliance processes. ***BARDA may suspend or terminate the BARDA Contract should we fail to achieve key milestones or fail to comply with the operating procedures and processes approved by BARDA and its audit agency. There can be no assurance that we will be able to achieve these milestones or continue to comply with these procedures and protocols, and there can also be no assurance that the BARDA Contract will not be terminated, that the BARDA Contract will be extended through the exercise of the gating periods, that any such extensions would be on terms favorable to us, or that we will otherwise obtain the funding that we anticipate to obtain under***

> ***the BARDA Contract***. The availability and focus for any BARDA funding will likely be finite and may require us to compete with other technologies, both similar and disparate. If the BARDA Contract is terminated or suspended, if there is any reduction or delay in funding under the BARDA Contract, or if BARDA determines not to elect to pursue any of the gated stages under the BARDA Contract, our revenues and cash flows would be significantly and negatively impacted and we may be forced to seek alternative sources of funding, which may not be available on non-dilutive terms, terms favorable to us or at all. If alternative sources of funding are not available, we may be forced to suspend or terminate development activities for our next-generation self-amplifying mRNA vaccine candidate containing Spike plus other viral targets to protect against COVID-19, which could materially harm our business.

92. The statements identified in bold and italicized text in the paragraphs above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as more fully described above, Gritstone failed to disclose that: (1) Gritstone currently did not have the necessary cGMP materials to manufacture and process the vaccine components in the CORAL vaccine study, and knew it would not be able to procure those materials in time to meet the Contract's base period requirements; (2) this known failure to meet the Contract's cGMP requirements would delay or cancel the Contract, and certainly would not provide the Company with the needed funding to fuel the study (3) the risks (including financial risks) posed by a failure to procure the necessary cGMP grade materials at its vendor sites was not merely hypothetical.

93. In the November 2, 2023 10-Q, the quarterly report also noted "there have been no material changes to the risk factors set forth in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 9, 2023," including the risk factors posing that "[a]ll internal and third-party contract manufacturing is performed under cGMP or similar guidelines."

94. Appended to the November 2, 2023 10-Q as an exhibit was a signed certification pursuant to the Sarbanes-Oxley Act of 2002 by the Individual Defendants, attesting that "[t]he information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company."

95. On February 12, 2024, Gritstone issued a Form 8-K, regarding the "Results of Operations and Financial Condition," stating:

> ***Gritstone bio, Inc. (the "Company") estimates that its cash, cash equivalents, marketable securities and restricted cash as of December 31, 2023 was approximately $86.9 million, inclusive of estimated contribution revenue of approximately $9.0 million for the year ended December 31, 2023, from the Company's contract with the Biomedical Advanced Research and Development Authority ("BARDA")***, a component of the Administration for Strategic Preparedness and Response in the U.S. Department of Health and Human Services, dated September 27, 2023 (as amended, the "BARDA Contract"). The Company's actual consolidated cash, cash equivalents, marketable securities and restricted cash balance and its contribution revenue from BARDA under the BARDA Contract as of December 31, 2023 are preliminary, unaudited and may differ from these estimates due to the completion of the Company's year-end closing and auditing procedures. ***These results were prepared by management and were based on the most current information available to management***, and are subject to completion by management of the financial statements as of and for the year ended December 31, 2023, including performance of the Company's financial closing procedures, any final adjustments and other developments that may arise between now and the time the financial results for this period are finalized, and the completion of the external audit of such financial statements. The Company's independent registered public accounting firm has not audited, reviewed, compiled, or applied agreed-upon procedures with respect to the preliminary financial data included herein. Accordingly, the Company's independent registered public accounting firm does not express an opinion or any other form of assurance with respect thereto.
>
> ***Based on the Company's current business plans and assumptions, including its updated timeline for the Company's Phase 2b clinical trial of its next-generation self-amplifying mRNA vaccine candidate against COVID-19, GRT-R924 (the "Phase 2b Trial") and changes in estimates to related BARDA reimbursements, the Company estimates its cash runway will be sufficient to fund the Company's operations into the third quarter of 2024.***

> ***Item 8.01 Other Events.***
> ***On February 12, 2024, the Company announced its decision to postpone the Phase 2b Trial until the fall of 2024 rather than the first quarter of 2024. The Company made this decision following communications with the U.S. Food and Drug Administration (the "FDA") with respect to the Company's investigational new drug application relating to the Company's next generation COVID-19 vaccine candidate, GRT-R924, intended to be tested in the Phase 2b Trial. The FDA informed the Company that, with respect to the Phase 2b Trial, the Company would be required to use fully GMP-grade materials, as well as implement certain other minor changes. The Company's other programs are not affected by this development.***

96. The statements identified in bold and italicized text in the paragraphs above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as more fully described above, Gritstone failed to disclose that: (1) Gritstone did not have the necessary cGMP materials to manufacture and process the vaccine components in the CORAL vaccine study, and knew it would not be able to procure those materials in time to meet the Contract's updated timeline for the base period requirements; (2) this known failure to meet the Contract's cGMP requirements would not provide the Company with the needed funding to fuel the into the third quarter of 2024; and (3) at the time, the Company already had been notified that the FDA had placed the CORAL program on a clinical hold.

97. On February 12, 2024, Gritstone issued a press release entitled "Gritstone bio Announces Update to Comparative Phase 2b COVID-19 Clinical Trial." The press release stated, in relevant part:

> ***Gritstone bio [. . .] today announced that it is now preparing to launch the Phase 2b head-to-head trial of its next-generation COVID-19 vaccine in the Fall of 2024 rather than 1Q24. This is to allow use of fully GMP-grade raw materials in the vaccine, which is expected to increase the regulatory utility of the trial***.

> "***After recent communication with the FDA and input from our colleagues at BARDA, we are now making the necessary preparations to begin the Phase 2b study later this year using fully GMP-grade materials in the manufacture of our self-amplifying mRNA (samRNA) vaccine***," said [Defendant] Allen[.] "***The change likely increases the regulatory value of this large study, is expected to improve study interpretability, and may enable us to contemporaneously address the latest seasonal variant***. We would like to thank the FDA for their collaboration and BARDA for their teamwork in support of this study, which aims to help deliver to the world a broader and more durable vaccine against COVID-19."

98. The statements identified in bold and italicized text in the paragraphs above were materially false and misleading when made, or omitted to state material facts necessary to make the statements not misleading, because, as more fully described above, Gritstone failed to disclose that: (1) Gritstone did not have the necessary cGMP materials to manufacture and process the vaccine components in the CORAL vaccine study, and knew it would not be able to procure those materials in time to meet the Contract's updated timeline for the base period requirements; (2) this known failure to meet the Contract's cGMP requirements would not provide the Company with the needed BARDA funding to fuel the into the third quarter of 2024; and (3) at the time, the Company already had been notified that the FDA had placed the CORAL program on a clinical hold.

VI. GRITSTONE'S CLASS PERIOD FILINGS DID NOT COMPLY WITH SEC DISCLOSURE REQUIREMENTS.

99. Gritstone's SEC filings identified above also failed to identify and disclose known trends, events, demands, commitments, and uncertainties that were then having and were reasonably likely to have a material effect on Gritstone's operating performance.

100. Item 7 of Form 10-K and Item 2 of Form 10-Q require SEC registrants to furnish the information called for under Item 303 of Regulation S-K [17 C.F.R. § 229.303], Management's Discussion and Analysis of Financial Condition and Results of Operations

("MD&A"). Among other things, Item 303 of Regulation S-K required that Gritstone's Class Period Forms 10-K and 10-Q disclose known trends or uncertainties that had, or were reasonably likely to have, a material impact on its revenues or income from continuing operations.

101. Similarly, Item 105 of Regulation S-K, 17 C.F.R. §229.105 ("Item 105"), required in the "Risk Factors" section of filings "a discussion of the [most significant] factors that make [the offering] . . . speculative or risky" and requires each risk factor to "adequately describe[] the risk."

102. In 1989, the SEC issued interpretative guidance associated with the requirements of Item 303 of Regulation S-K concerning the disclosure of material trends or uncertainties. As the interpretative guidance states:

> Required disclosure is based on currently known trends, events, and uncertainties that are reasonably expected to have material effects, such as: A reduction in the registrant's product prices; erosion in the registrant's market share; changes in insurance coverage; or the likely non-renewal of a material contract…..
>
> A disclosure duty exists where a trend, demand, commitment, event or uncertainty is both presently known to management and reasonably likely to have material effects on the registrant's financial condition or results of operation.

103. The 1989 Interpretive Release sets forth the following test to determine if disclosure under Item 303(a) is required:

104. Where a trend, demand, commitment, event or uncertainty is known, management must make two assessments:

> Is the known trend, demand, commitment, event or uncertainty likely to come to fruition? If management determines that it is not reasonably likely to occur, no disclosure is required.
> If management cannot make that determination, it must evaluate objectively the consequences of the known trend, demand, commitment, event or

> uncertainty, on the assumption that it will come to fruition. Disclosure is then required unless management determines that a material effect on the registrant's financial condition or results of operations is not reasonably likely to occur.

105. Additionally, the SEC published interpretive guidance, effective December 29, 2003, "regarding the disclosure commonly known as Management's Discussion and Analysis of Financial Condition and Results of Operations, or MD&A, which is required by Item 303 of Regulation S-K, Items 303(b) and (c) of Regulation S-B, Item 5 of Form 20-F and Paragraph 11 of General Instruction B of Form 40-F." In particular, the SEC advised that "companies must identify and disclose known trends, events, demands, commitments and uncertainties that are reasonably likely to have a material effect on financial condition or operating performance," citing the 1989 Interpretive Release as support and quoting, in footnote 6, the following text of the 1989 Interpretive Release:

> MD&A mandates disclosure of specified forward-looking information, and specifies its own standards for disclosure – i.e., reasonably likely to have a material effect. The specific standard governs the circumstances in which Item 303 requires disclosure….
>
> We believe that management's most important responsibilities include communicating with investors in a clear and straightforward manner. MD&A is a critical component of that communication. The Commission has long sought through its rules, enforcement actions and interpretive processes to elicit MD&A that not only meets technical disclosure requirements but generally is informative and transparent.

106. Thus, the MD&A disclosures in Gritstone's Forms 10-K and 10-Q it filed with the SEC during the Class Period were materially false and misleading because Defendants failed to disclose the known uncertainties associated with Gritstone's known failure to meet the necessary cGMP requirements to initiate the CORAL Phase 2 study. As a result, these were events presenting known trends, uncertainties, and risks that were reasonably likely to—and, when they came to fruition during the Class Period, did—

adversely affect Gritstone's financial condition and results. The omission of this information violated the disclosure obligation imposed by Item 303 and Item 105.

VII. THE TRUTH BEGINS TO EMERGE.

107. On February 29, 2024, Gritstone issued a press release entitled "Gritstone bio Announces Workforce Reduction." The press release stated, in relevant part:

> Gritstone [. . .] today announced an approximately 40% reduction of its workforce. The move comes following the recently announced delay of the proposed CORAL Phase 2b study, which resulted in Gritstone not receiving external funding it previously anticipated beginning in 1Q 2024, associated with the initiation of the study.
>
> "The lack of near-term funding necessitated this difficult step to fortify our balance sheet and cash position, which unfortunately means an impact to our workforce," said [Defendant] Allen[.] "I would like to express my sincere thanks to our departing employees for their contributions and reiterate our enthusiasm for the programs that they have helped build."

108. On this news, Gritstone's stock price fell $0.78 per share, or 27.86%, to close at $2.02 per share on March 1, 2024. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiffs and other Class members have suffered significant losses and damages.

109. Gritstone continued to represent that its CORAL Phase 2 study would be ongoing in its March 5, 2024 press release and annual report.

110. On March 5, 2024, Gritstone issued a press release, entitled "Gritstone bio Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Corporate Updates," quoting Defendant Allen stating:

> [T]he ***recent decision to incorporate GMP-grade materials*** in the manufacture of our self-amplifying mRNA (samRNA) candidate enhances the potential regulatory utility of the Phase 2b CORAL-BARDA study, as well as our broader platform, an important development ***as we prepare to launch the study later this year*** ….

> As the calendar flips further into 2024, Gritstone continues marching forward toward potentially enabling the full potential of our novel vaccine platforms in both oncology and infectious disease.

111. Under the "Corporate Update" section of the press release: "In February 2024, Gritstone bio reduced its workforce by approximately 40% to reduce costs and preserve capital. The reduction primarily impacted employees associated with vaccine manufacturing and clinical infectious disease operations, who were not active in the ongoing Phase 2 study of GRANITE, Gritstone's personalized cancer vaccine," and "[t]he reduction occurred approximately two weeks following the previously announced delay of the proposed CORAL Phase 2b study, which resulted in Gritstone not receiving external funding it previously anticipated beginning in 1Q 2024, associated with the initiation of the study."

112. Under the "Clinical Program Updates, Infectious Disease Programs," for "CORAL," the "[n]ext-generation SARS-CoV-2 vaccine program that serves as proof-of-concept for Gritstone's samRNA platform and novel approach in infectious diseases," the press release stated:

> In February 2024, Gritstone announced it will incorporate GMP-grade materials in the manufacture of its self-amplifying mRNA (samRNA) candidate, resulting in a delay of the CORAL Phase 2b study (CORAL-BARDA). The move is expected to increase the regulatory utility of the anticipated 10,000 subject, comparative Phase 2b study contracted by the Biomedical Advanced Research and Development Authority (BARDA) Gritstone is now preparing to launch the study in Fall 2024.…
>
> This project has been supported in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract number 75A50123C0006.

113. In the March 5, 2024 annual report, the Company reiterated the "going concern" warning, and noted under "New Developments," that:

On February 12, 2024, we announced that we are preparing to launch the Phase 2b trial of our next-generation COVID-19 vaccine supported by BARDA in the Fall of 2024 rather than first quarter of 2024. This is to allow use of GMP-grade raw materials in our samRNA vaccine, which is expected to increase the regulatory utility of the trial. This decision was made following communications with the FDA.

114. Under "CORAL Regulatory Milestones," the Company stated:

In November 2023, we submitted an IND application to the FDA for our Phase 2b CORAL Study designed to evaluate our next-generation CORAL vaccine candidate against COVID-19. In December 2023, we were notified by the FDA that our Phase 2b CORAL Study had been placed on clinical hold. In January 2024, we received the formal clinical hold letter from the FDA, identifying certain CMC and clinical deficiencies. The FDA informed us that, among other changes, we will be required to use GMP-grade materials in the manufacture of the vaccine as well as implement minor changes in the clinical trial protocol. We are working on preparing a complete response to the FDA's letter in an effort to remove the clinical hold from our IND application. This includes re-manufacturing our CORAL vaccine candidate to be used in the Phase 2b CORAL Study with GMP-grade materials.

115. Under "Item 1A. Risk Factors," the 10-K stated:

It may take considerable time and expense to resolve the clinical hold that has been placed by the FDA on our Phase 2b CORAL trial we proposed in our IND for our CORAL COVID-19 vaccine product candidate and no assurance can be given that the FDA will remove the clinical hold, in which case our business and financial prospects may be materially adversely affected.

In December 2023, we were notified by the FDA that our Phase 2b CORAL Study had been placed on clinical hold. In January 2024, we received the formal clinical hold letter from the FDA, identifying certain CMC and clinical deficiencies. The FDA informed us that, among other changes, we will be required to use GMP-grade materials in the manufacture of the vaccine as well as implement minor changes in the clinical study protocol. We are working on preparing a complete response to the FDA's letter in an effort to remove the clinical hold from our IND application. This includes remanufacturing our CORAL vaccine candidate to be used in the Phase 2b CORAL Study with GMP-grade materials. If the FDA does not accept the responses we plan to provide, it may take a further considerable period of time, the length of which is not certain at this time, and additional expense for us to fully address the FDA's concerns. It is possible that we will be unable to fully address the FDA's concerns and, as a result, that the clinical

> hold may never be lifted and we may never be able to initiate our Phase 2b CORAL Study in the United States, which could have a material adverse effect on our business, financial condition, results of operations and prospects.
> …..
> A significant portion of the funding for the continued development of our next-generation samRNA vaccine candidate containing Spike plus other viral targets to protect against COVID-19 is currently expected to come from BARDA funds, whether under the BARDA Contract or as administered through the RRPV Consortium. If BARDA were to decline to pursue any of the gated stages, eliminate, reduce, delay, or object to extensions for funding available to us under the BARDA Contract, this could have a significant, negative impact on our revenues and cash flows, and we may be forced to suspend or terminate the continued development of the product candidate or obtain alternative sources of funding.

116. Soon after, on April 1, 2024, the Company filed an 8-K announcing that "it has commenced an underwritten public offering of shares of its common stock" to shore up the Company's liquidity crisis, a pronouncement that sent the stock falling $1.15 per share, or 48.94%, to close at $1.20 per share on April 2, 2024. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiffs and other Class members have suffered significant losses and damages.

VIII. POST-CLASS PERIOD DEVELOPMENTS.

117. On October 10, 2024, Gritstone declared Chapter 11 bankruptcy seeking "to preserve value and support its ongoing strategic alternatives process."[1] Gritstone also announced further layoffs and that it would be delisted from NASDAQ trading effective October 22, 2024.[2]

[1] https://ir.gritstonebio.com/news-releases/news-release-details/gritstone-bio-takes-action-preserve-value-and-strengthen-capital
[2] https://www.investing.com/news/company-news/gritstone-bio-announces-layoffs-and-nasdaq-delisting-93CH-3667285

IX. ADDITIONAL FACTS PROBATIVE OF SCIENTER.

118. The Individual Defendants acted with scienter because at the time they issued public documents and other statements in Gritstone's name, they knew, or with extreme recklessness disregarded the fact that such statements were materially false and misleading or omitted material facts. The Individual Defendants knew such documents and statements would be issued or disseminated to the investing public, knew that persons were likely to rely upon those misrepresentations and omissions, and knowingly and recklessly participated in the issuance and dissemination of such statements and documents as primary violators of the federal securities laws.

119. A holistic examination of the facts and circumstances, including those set forth below, collectively supports a strong inference that throughout the Class Period, Defendants knew or, at a minimum, recklessly disregarded, that their statements were materially false and misleading.

A. The Individual Defendants Conferred with the FDA on the CORAL Phase 2 Study.

120. The Individual Defendants expressly conferred with the FDA regarding the CORAL Phase 2 study design, protocols, and materials. In its filings with the SEC, Defendants acknowledged these "Interactions with the Regulatory Health Authorities," where in a pre-IND "interaction with the FDA was conducted to review the proposed clinical investigation" for CORAL, where "[t]he FDA concluded that the overall manufacturing and release testing for the CORAL vaccines candidates … appeared acceptable and requested detail on the transfection process, grade of materials, and release tests be submitted in the IND." (Annual Report for 2022, Form 10-K, filed March 9, 2023.) That the FDA requested more information about the "grade of materials" to be used it the CORAL study supports the

inference that the Individual Defendants were aware of the FDA's mandates for cGMP materials in Phase 2 studies, and that the current lack of cGMP grade material at Gritstone would roadblock any viable Phase 2 study launch.

B. BARDA Funding Was Critical to Gritstone's Continued Operations.

121. It is reasonable to infer that Defendants were aware of the cGMP supply failures given how important meeting the Contract's schedule was to Gritstone's continued operations. Because Gritstone has no commercial-stage products, the vast majority of its vaccine programs are being funded via external collaborators, such as BARDA. Throughout 2023, Gritstone faced an increasing liquidity crisis, forcing the Company to issue a "going concern warning" in August 2023, one month before announcing the BARDA Contract, when the Company admitted its "cash, cash equivalents and marketable securities are not sufficient to fund the Company's planned operations for a period of 12 months." (Q2 Quarterly Report, Form 10-Q, filed August 9, 2023.)

122. But, given this forthcoming influx of cash from BARDA, Defendants could posit that, "[t]he Company estimates that, based on the fees payable and anticipated reimbursement of certain expenses to the Company under the BARDA Contract, the Company's cash runway will be extended into the fourth quarter of 2024." (Form 8-K, filed Sept. 27, 2023.) As the Company disclosed in its November 2023 10-Q, "if BARDA were to decline to pursue any of the gated stages, eliminate, reduce, delay, or object to extensions for funding available to us under the BARDA Contract, this could have a significant, negative impact on our revenues and cash flows, and we may be forced to suspend or terminate the continued development of the product candidate or obtain alternative sources of funding." This warning came to pass: Indeed, following the failure to comply with the BARDA

timelines, Gritstone spiraled into a cash deficit leading to bankruptcy. Thus, that Gritstone was so dependent on this funding for its continued operations demonstrates that Defendants were aware of the Contract's cGMP requirements and the Company's lack of compliance with them.

C. The Individual Defendants Knew or Should Have Known of the Status of Gritstone's cGMP Manufacturing and Quality Processes.

123. As expanded above, Defendants repeatedly touted the Company's ability to produce its vaccines in-house and in compliance with all necessary cGMP requirements. The signed for 10-K, for instance, avowed that "[w]e manufacture our products at our own fully-integrated good manufacturing practice (GMP) biomanufacturing facilities" and recognized that "[o]ur ability to control the manufacturing of high-quality vaccine products, and scale production, if early data are positive, is critical for efficient clinical development and commercialization." (Annual Report for 2022, Form 10-K, filed March 9, 2023.) Not only did Defendants assure the market about these robust in-house quality control measures, they also represented that any farming out of those processes to third parties also complied with cGMP: "[a]ll internal and third-party contract manufacturing is performed under cGMP or similar guidelines." (Annual Report for 2022, Form 10-K, filed March 9, 2023.) These pledges of quality raise the inference that Defendants were familiar with the Company's cGMP status in producing its vaccines and knew cGMP compliance was critical to the business' success. Alternatively, if the Individual Defendants were not knowledgeable about the matters on which they purported to speak in detail, such recklessness would readily satisfy the scienter requirement.

D. The Individual Defendants Were Intimately Aware of the Significant cGMP Failings for the CORAL Phase 2 Study Throughout the Class Period.

124. As provided above, a Director of Quality Control at Gritstone confirms that management was well aware of the Company's ongoing failure to secure the requisite cGMP materials needed to launch CORAL Phase 2 and/or to comply with the BARDA Contract. CW1 joined the Company six months before the BARDA contract, in March 2023, and, by that time, witnessed that the Company already was scrambling to secure these cGMP-grade materials and had assembled a task force to procure them (of which CW1 was a member). According to the CW1, COO Jones regularly "informed CEO Andrew Allen about the status of the task force's work, including details about the inability to acquire GMP-grade raw materials by early 2024" to comply with the terms of the BARDA Contract. In addition, CW1 "had conversations with COO Jones about the status of the procurement efforts," and conveyed how COO Jones "was informed at every step about which GMP-grade raw materials were procured and which of the raw materials had not yet been procured at GMP-grade" and that the COO regularly conveyed this status to the CEO. This real-time information would have alerted the CEO to these ongoing (and un-remediated) efforts to secure cGMP materials for the Phase 2 study.

E. The Individual Defendants' Expertise Demonstrates That They Were Aware Of or Recklessly Disregarded The Import of Gritstone's Failure to Secure cGMP Materials.

125. Gritstone boasted that it employs a deep bench of industry experts leading the push to develop the CORAL vaccine. "To deliver on the promise of our novel therapeutic approaches, we have assembled an experienced leadership team with deep expertise in each of our core disciplines of immunotherapy research … clinical and regulatory development, and biomanufacturing." (Gritstone Website, "Our Leadership," available at

https://gritstonebio.com/about/.) As of December 31, 2022, the Company "had 233 full-time employees, including a total of 54 employees with M.D. or Ph.D. degrees." (Annual Report for 2022, Form 10-K, filed March 9, 2023.) Indeed, half of the Company's "Leadership" roles have Ph.Ds. (Gritstone Website, "Our Leadership," available at https://gritstonebio.com/about/.) And of the seven Board of Directors, five members have Ph.Ds. or M.D.s—and one member has both. (Gritstone Website, "Our Leadership," available at https://gritstonebio.com/about/.)

126. Defendant Allen, "Co-founder, President and Chief Executive Officer," has an M.D. from Oxford University and a Ph.D. in Immunology from Imperial College. (Gritstone Website, "Our Leadership," available at https://gritstonebio.com/about/.) Prior to co-founding Gritstone bio in 2015, Dr. Allen co-founded and was CMO at other immunology companies, and he serves on the Board of Directors at several immunology related entities. (Gritstone Website, "Our Leadership," available at https://gritstonebio.com/about/.) In addition, Defendant Economides, Gritstone's "Executive Vice President and Chief Financial Officer," has a B.A. from McGill University and an M.P.H. in Health Policy and Management from Columbia University. (Gritstone Website, "Our Leadership," available at https://gritstonebio.com/about/.). And, before joining Gritstone in 2021, Defendant Economides held senior management positions at other public companies developing immunotherapy treatments and has decades of experience in this industry. (Gritstone Website, "Our Leadership," available at https://gritstonebio.com/about/.). With this technical, relevant background, Defendants would have known about the FDA's requirement that all Phase 2 studies be conducted using cGMP materials and would have known that

Gritstone's failure to procure those materials would not be negotiable for a government-funded contract like BARDA.

X. PLAINTIFFS' CLASS ACTION ALLEGATIONS

127. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Gritstone securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

128. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Gritstone securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Gritstone or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

129. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

130. Plaintiffs will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

131. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Gritstone;
- whether the Individual Defendants caused Gritstone to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Gritstone securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

132. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

133. Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

1. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

2. the omissions and misrepresentations were material;

3. Gritstone securities are traded in an efficient market;

4. the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;

5. the Company traded on the NASDAQ and was covered by multiple analysts;

6. the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

7. Plaintiff and members of the Class purchased, acquired and/or sold Gritstone securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

134. Based upon the foregoing, Plaintiffs and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

135. Alternatively, Plaintiffs and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

XI. COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

136. Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein.

137. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

138. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiffs and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Gritstone securities; and (iii) cause Plaintiffs and other members of the Class to purchase or otherwise acquire Gritstone securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

139. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Gritstone securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Gritstone's finances and business prospects.

140. By virtue of their positions at Gritstone, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiffs and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

141. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Gritstone, the Individual Defendants had knowledge of the details of Gritstone's internal affairs.

142. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Gritstone. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Gritstone's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Gritstone securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Gritstone's business and financial condition which were concealed by Defendants, Plaintiffs

and the other members of the Class purchased or otherwise acquired Gritstone securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

143. During the Class Period, Gritstone securities were traded on an active and efficient market. Plaintiffs and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Gritstone securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiffs and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiffs and the Class, the true value of Gritstone securities was substantially lower than the prices paid by Plaintiffs and the other members of the Class. The market price of Gritstone securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiffs and Class members.

144. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

145. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon

the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

XII. COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

146. Plaintiffs repeat and re-allege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

147. During the Class Period, the Individual Defendants participated in the operation and management of Gritstone, and conducted and participated, directly and indirectly, in the conduct of Gritstone's business affairs. Because of their senior positions, they knew the adverse non-public information about Gritstone's misstatement of income and expenses and false financial statements.

148. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Gritstone's financial condition and results of operations, and to correct promptly any public statements issued by Gritstone which had become materially false or misleading.

149. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Gritstone disseminated in the marketplace during the Class Period concerning Gritstone's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Gritstone to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Gritstone within the meaning of Section 20(a) of the Exchange Act.

In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Gritstone securities.

150. Each of the Individual Defendants, therefore, acted as a controlling person of Gritstone. By reason of their senior management positions and/or being directors of Gritstone, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Gritstone to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Gritstone and possessed the power to control the specific activities which comprise the primary violations about which Plaintiffs and the other members of the Class complain.

151. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Gritstone.

XIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

1. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

2. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

3. Awarding Plaintiffs and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

4. Awarding such other and further relief as this Court may deem just and proper.

XIV. DEMAND FOR TRIAL BY JURY

Plaintiffs hereby demand a trial by jury.

Dated: November 8, 2024

Respectfully submitted,

POMERANTZ LLP

/s/ Jennifer Pafiti

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Attorneys for Plaintiffs

CERTIFICATION PURSUANT
TO FEDERAL SECURITIES LAWS

1. I, Tammy Beal, make this declaration pursuant to Section 27(a)(2) of the Securities Act of 1933 ("Securities Act") and/or Section 21D(a)(2) of the Securities Exchange Act of 1934 ("Exchange Act") as amended by the Private Securities Litigation Reform Act of 1995.

2. I understand that by order dated September 10, 2024, the Court appointed Richard Rodriguez as Lead Plaintiff in this litigation. I am willing to continue to serve as a representative party on behalf of a Class of investors who purchased or otherwise acquired Gritstone bio, Inc. ("Gritstone") securities during the Class Period as specified in the Amended Complaint For Violations Of The Federal Securities Laws (the "Amended Complaint"), including providing testimony at deposition and trial, if necessary.

3. I have reviewed the initial Complaint against Gritstone, and the pertinent lead plaintiff filings in this action, and authorize the filing of a comparable amended complaint on my behalf.

4. I did not purchase or acquire Gritstone securities at the direction of plaintiffs' counsel or in order to participate in any private action arising under the Securities Act or Exchange Act.

5. The attached sheet lists all of my transactions in Gritstone securities during the Class Period as specified in the Amended Complaint.

6. During the three-year period preceding the date on which this Certification is signed, apart from this action, I have not served or sought to serve as a representative party on behalf of a class under the federal securities laws.

7. I agree not to accept any payment for serving as a representative party on behalf of the Class as set forth in the Amended Complaint, beyond my pro rata share of any recovery, except such reasonable costs and expenses directly relating to the representation of the class as ordered or approved by the Court.

8. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed 11/8/2024 **(Date)**

DocuSigned by:

6EFF620774204FA...

(Signature)

Tammy Beal

(Type or Print Name)

Gritstone bio, Inc. (GRTS) **Tammy Beal**

List of Purchases/Acquisitions and Sales

Transaction Type	Date	Number of Shares/Unit	Price Per Share/Unit
Purchase/Acquisition	9/21/2023	78.895416	$1.2700
Purchase/Acquisition	9/22/2023	39.082430	$1.2800
Purchase/Acquisition	10/24/2023	25.000000	$1.9200
Purchase/Acquisition	11/1/2023	3.444430	$1.8100
Purchase/Acquisition	11/9/2023	30.769230	$1.6300
Purchase/Acquisition	11/27/2023	37.735849	$1.3300
Purchase/Acquisition	12/5/2023	31.448590	$1.5900
Purchase/Acquisition	12/15/2023	26.602819	$1.8800